510(k) Summary of Safety and Effectiveness
Disc-O-Tech Medical Technologies, Ltd.'s *Bonus* Orthopedic Bone Screw Fixation System

510(k) Number K011390

JUN - 6 2001

This 510(k) notification is submitted by Disc-O-Tech Medical Technologies Ltd. The contact person is Mr. Elad Magal, General Manager.

This 510(k) notification describes a device intended for soft tissue fixation to bones by means of bone screws threaded with sutures. The *Bonus* Orthopedic Bone Screw Fixation System is indicated for use during surgical procedures where soft tissue fixation to bones is needed, such as:

1. Repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromiociavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction.
2. Repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation.
3. Repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament.
4. Repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis.
5. Repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

The *Bonus* – Orthopedic Bone Screw Fixation System is substantially equivalent to Influence, Inc.'s *Straight-In* – Orthopedic Bone Screw Fixation System cleared under K990055. The design and materials of the *Bonus* and *Straight-In* Orthopedic systems are substantially equivalent. The *Bonus* device is also substantially equivalent to Orthopedic Biosystems, Ltd., Inc. 6.5mm PeBA® C Anchor cleared under K951451 with respect to intended use and performance of the bone screws.

Information and performance testing provided and referenced in the application demonstrates equivalence to the predicate devices with respect to performance.

Based on the information provided, the *Bonus* - Orthopedic Bone Screw Fixation System is substantially equivalent to the *Straight-In* - Orthopedic Bone Screw Fixation System and to the PeBA® C Anchor with respect to intended use, technological characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Elad Magal
General Manager
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnoat Street
Herzeliya, Israel 46728

Re: K011390
Trade/Device Name: Bonus - Orthopedic Bone Screw Fixation System
Regulation Number: 888.3040
Regulatory Class: II
Product Code: MBI, HWC
Dated: May 2, 2001
Received: May 7, 2001

Dear Mr. Magal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011390

Device Name: *Bonus* – Orthopedic Bone Screw Fixation System.

Indications for Use:

The *Bonus* - Orthopedic Bone Screw Fixation System is intended for soft tissue fixation to bones by means of bone screws threaded with sutures.

It is indicated for use during surgical procedures where soft tissue fixation to bones is needed, such as:

1. Repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromiociavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction.
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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

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Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use____

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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